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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,180

03/23/2005

Peng Liu

514572002400

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25225 7590 01/24/2008

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

KAFIMOSAVI, HOSEIN

ART UNIT

PAPER NUMBER

4132

MAIL DATE

DELIVERY MODE

01/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,180	Applicant(s) LIU ET AL.	
	Examiner HOSEIN KAFIMOSAVI	Art Unit 4132	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/27/2007, 10/22/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1-3 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhao et al. (US 6,939,451 B2) ("Zhao").

As to claim 1, Zhao discloses a capillary electrophoresis chip apparatus (10) (capable of detecting nucleotide polymorphism or single nucleotide polymorphism) (Col.14, 34-43) that comprises: an electrophoresis chip having an upper planar substrate (18) having one or more microchannels (14) and one or more apertures (24) (Col.5, 55-58) for loading samples; a middle electrode layer (20) (cover layer with integrated electrode components; Col.12, 28-34) that bonds to the bottom of the substrate enclosing and sealing the microchannels to form an intact capillary and providing the voltage for electrophoresis; and a lower heating layer (301) (Fig. 7C and

Col. 13, 45-47) wherein the individual layers are thermal conductive and adhesive to each other (Col. 12, 21-23).

The reference discloses that the heating layer may comprise heaters placed within certain localized regions along the microchannels (column 13, lines 45-47). Therefore, one of ordinary skill in the art would appreciate that the heating layer of Zhao would be capable of providing a stable temperature gradient.

As to claim 2, Zhao discloses a one dimensional microchannel (14) and the possibility of multidimensional microchannels (Figure 1 and Column 10, lines 13-15).

As to claim 3, Zhao discloses a width, depth or diameter of the microchannels being between 1 to 200 μm (Col.6, 2-5) and a separation length of 18.5 cm (Col.15, 12-13). As to claim 6, Zhao teaches two or more sets of heaters spaced apart (column 13, lines 44-49) that would be capable of being at different constant temperature to form a spatial temperature gradient.

As to claim 7, the heaters of Zhao would be capable of establishing a temporal temperature gradient.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (US 6,939,451 B2) ("Zhao") in view of Kaltenbach et al. (EP 0,770,871 A3, listed in IDS) ("Kaltenbach").

As to claim 1, the Examiner took the position that the heating layer (301) of Zhao would be capable of providing a stable temperature gradient. However, if it is not taken that the heating layer of Zhao would be capable of providing a stable temperature gradient; the following rejection is set forth to expedite prosecution.

Zhao discloses a bottom heating layer (301) to heat the chip (Figure 7c) where the heating layer may comprise heaters placed within certain localized regions along the microchannels (column 13, lines 28-31 and 45-47).

Kaltenbach discloses a capillary electrophoresis chip comprising a miniaturized column device and a lower heating layer comprising heating elements (146 c, d and e; Figure 10). The heating elements are in thermal contact with the middle layer and can be independently set to different temperatures thereby producing a temperature

gradient across the middle layer for increasing sample processing efficiency (column 25, lines 7-14 and 36-39 and 45-49).

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the heaters comprising the lower heating layer of Zhao be independently set to different temperatures to produce a stable temperature gradient, as taught by Kaltenbach, a temperature gradient can improve the microfluidic chip by increasing sample processing efficiency.

As to claims 2-3, please refer to the rejections set forth above.

As to claim 6, Zhao teaches two or more sets of heaters spaced apart (column 13, lines 44-49) and Zhao, as modified in view of Kaltenbach, teaches the heaters at different constant temperature to form a spatial temperature gradient.

As to claim 7, Zhao, as modified in view of Kaltenbach, teaches a temporal temperature gradient (Kaltenbach at column 25, lines 1-15).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (US 6,939,451 B2) ("Zhao"), or alternatively Zhao in view of Kaltenbach, as applied to claim 1 above, and further in view of Harvey A. Hodes (US 3,502,558) ("Harvey").

As to claim 4, Zhao further discloses that the specific design and composition of the driving electrodes on the middle cover layer should be understood by those skilled in the art to be electrically conductive.

Zhao does not disclose the specific examples used in electrodes that are electrically conductive.

Harvey discloses a method of depositing gelatin on electrodes made of electrically conductive material such as gold, platinum or graphite.

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the middle cover layer with integrated electrode components (Col.12, 28-34) that bonds to the bottom of the substrate enclosing and sealing the microchannels and providing the voltage for electrophoresis where the integrated electrodes are made of electrically conductive material such as gold, platinum or graphite, as taught by Harvey, in the invention of Zhao because Zhao already provides electrodes and as taught by Harvey the suitable electrode material can be any of gold, platinum or graphite because they are electrically conductive (Col.1, 63-65).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (US 6,939,451 B2) ("Zhao"), or alternatively Zhao in view of Kaltenbach, as applied to claim 1 above, and further in view of Johnck et al. (US 2003/0161572 A1) ("Johnck").

As to claim 5, Zhao further discloses that the middle cover layer can be coated with a pressure sensitive adhesive which is then pressed against the substrate containing channels and wells.

Zhao does not disclose the specific examples of pressure sensitive adhesives that can be used to coat the middle cover layer.

Johnck discloses a microfluidic analysis system consisting of an upper substrate layer and a middle cover layer with thin-film electrodes integrated thereon. Furthermore,

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Johnck discloses that the cover can be coated with polydimethylsiloxane (PDMS) which will be electrically insulating the exposed electrodes.

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the middle cover layer with integrated electrode components (Col.12, 28-34) that bonds to the bottom of the substrate enclosing and sealing the microchannels and providing the voltage for electrophoresis to be coated where the pressure sensitive adhesive coating of the middle cover layer can be switched to a coating of polydimethylsiloxane (PDMS), as taught by Johnck, in the invention of Zhao because Zhao already provides a coating layer for the cover layer and as taught by Harvey the polydimethylsiloxane (PDMS) coating can electrically insulate the electrodes [0058].

Correspondence / Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOSEIN KAFIMOSAVI whose telephone number is (571)270-5271. The examiner can normally be reached on Mon - Fri, 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ward Jessica can be reached on (571) 272-1223. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. K./
Examiner, Art Unit 4132

/Jessica Ward/
Supervisory Patent Examiner, Art Unit 4132